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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/553,078

06/23/2006

Per Thor Straten

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08/06/2008

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/553,078 | Applicant(s) STRATEN ET AL. | |
| | Examiner CHRISTOPHER H. YAEN | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45 and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-7,12,14-16,18-21,24,27,30,32,33,35,37,39,41,45,47-49,51 and 53-59.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,2,4-7,12,14-16,18-21,24,27,30,32,33,35,37,39,41 and 47-49.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/2007 has been entered.

The amendment filed 7/20/2007 is acknowledged and entered into the record. Accordingly, claims 3,5-6,8-11,13,17,22-23,25-26,28-29,31,34,36,38,40,42-44,46,50,52, and 60-65 are canceled without prejudice or disclaimer. Claims 1-2,4-7,12,14-16,18-21,24,27,30,32-33,35,37,39,41,45,47-49,51,53-59 are pending, claims 1-2,4-7,12,14-16,18-21,24,27,30,32-33,35,37,39,41, and 47-49 are withdrawn as being drawn to a non-elected invention. Claims 45, 54-58, and 59 are examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

The rejection of claims 45, 54-58, and 59 under 35 USC § 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instant application is enabled for the claimed invention. Specifically, applicant argues that the examples provided in the specification teach the skilled artisan how to practice the claimed invention because the ELISPOT assay is predictive of clinical or in vivo outcomes. Applicant supports this contention by indicating that the ELISPOT

Art Unit: 1643

assay is suited for measuring CTL responses because it is both sensitive and reliable as a means for measuring immune responses. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

A conclusion of lack of enablement means that, based on the evidence regarding each of the *Wands* factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). In the instant case, the claims are drawn to the administration of a peptide into an individual for the purposes of generating an immune response. The prior art of record teaches that several attempts by others have failed to generate appropriate CTL responses in vivo against specific epitopes, whereby only a limited number of peptides were successful in generating an response. Although the ELISPOT assay is deemed to be a reliable method of determining if a T cell response has been generated, it alone is insufficient to show that the administration of a peptide would have the same effect and result given the unsuccessful attempts by others in the field. Applicants have not provided any objective evidence to indicate that the ELISPOT assay is in fact correlative to in vivo efficacy in light of the general unpredictable nature of CTL generation in vivo as taught in the prior art. What the applicant has show in the specification is an in vitro assay which shows that some peptides are capable of eliciting a CTL responses in vitro.

Therefore, the rejection of claims under 35 USC 112, 1st paragraph is maintained for the reasons of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER H. YAEN whose telephone number is (571)272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher H Yaen/
Primary Examiner, Art Unit 1643